

BOTTLE OF LIES

The Inside Story of the Generic Drug Boom

BY KATHERINE EBAN

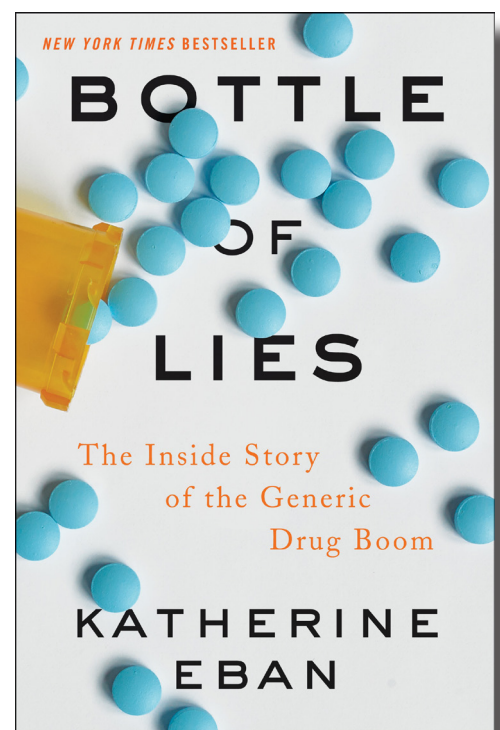
READING GROUP GUIDE

1. While *Bottle of Lies* centers on a dangerous fraud in a globalized world, it also offers a key narrative that integrity is possible. Malvinder Singh at Ranbaxy sits on one side of the equation. Dinesh Thakur and Peter Baker sit on the other. Discuss how globalization impacts personal conduct, public health and drug safety.

2. *Bottle of Lies* describes the FDA's painstaking approval process surrounding the world's biggest generic drug launch—for Ranbaxy's generic Lipitor. (Chapter 22, The \$600 Million Jacket) The agency knew the company was saturated in fraud. Yet, facing political pressure for a low-cost generic version and concerned that Ranbaxy would “park” its exclusive right to manufacture (denying competitors an opportunity to launch), the FDA approved the drug. Less than a year later, Ranbaxy's atorvastatin turned out to contain glass fragments, and had to be recalled. Discuss the FDA's role in balancing public safety against the public's need for low-cost drugs. What should the FDA have done, and what is its proper role?

3. At Ranbaxy, as Dinesh Thakur begins to learn about the company's massive data fraud, his colleague Arun Kumar asks him, “What is wrong with you guys who go to the U.S. for a few years and think you have become the moral police of the world? Do you think U.S. pharma companies never do such things?”(Chapter 9, The Assignment, p. 104) Discuss the interplay of corporate conduct and company culture. Also, given the long history of Big Pharma's transgressions, does Kumar have a point?

4. The book describes how generic companies routinely make drugs of different quality for different markets, depending on the vigilance of the regulators in other countries. This system, known as “dual track production,” amounts to a manufacturing standard of *whatever they can get away with*. (Chapter 26, The Ultimate Testing Laboratory) Discuss the ethical and public health implications of these disparate standards.



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5. The acquisition of Ranbaxy by Daiichi Sankyo unfolds as a culture clash (Chapter 16, Diamond and Ruby). As Ranbaxy's lawyer Jay Deshmukh puts it, the Indian and Japanese cultures were like "oil and water." Indians succeeded in business by being 'ultra-aggressive,' he said. 'Ethics are not important.' By contrast, the Japanese were 'very trusting. Babes in the woods.'" (p. 201) Discuss Daiichi Sankyo's assumptions, and how cultural disconnect may contribute to global fraud.

6. The book describes a global cat-and-mouse game between FDA investigators and overseas the manufacturing plants they inspect. The plants use advanced notice of inspections to fabricate data, remove secret equipment and clean up insect and bird infestations. Discuss the FDA's approach to these inspections. What is the FDA doing right? Or doing wrong?

7. The book describes endemic fraud in the overseas manufacturing of generic drugs, which comprise 90 percent of the U.S. drug supply. As a consumer, has the book changed the way that you think about the safety of your medications? What do you think consumers should do—and what should they demand of the government—to safeguard their drugs?

8. What is your experience with getting prescriptions filled? What did you learn from this book that you didn't know before? Does this book strike terror in your heart?

